



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/594,941

03/13/2008

Roberta Martinetti

41416

5670

86378

7590

07/12/2010

Pearne & Gordon LLP

1801 East 9th Street

Suite 1200

Cleveland, OH 44114-3108

EXAMINER

STEWART, JASON-DENNIS NEILKEN

ART UNIT

PAPER NUMBER

3738

NOTIFICATION DATE

DELIVERY MODE

07/12/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@pearne.com

dchervenak@pearne.com

Office Action Summary	Application No. 10/594,941	Applicant(s) MARTINETTI ET AL.	
	Examiner JASON-DENNIS STEWART	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>26 December 2006, 28 September 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a Non-Final Office action in response to communications received on 09/28/2006. Claims 1-10 are currently pending and addressed below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 1, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

4. Regarding Claim 1, the phrase "porosity (30-90%)" is indefinite because it is unclear if the 30-90% range is required. It is suggested that the Applicant clearly describe the porosity in that range if desired.

5. Regarding Claim 1, the phrase "pore dimensions in the 0.1-125 microns and 125-2500 microns range" is indefinite because it could be interpreted as a pore range of 0.1-2500 microns or as requiring pores in each range listed. Appropriate correction is suggested.

Art Unit: 3738

6. Regarding Claims 6 and 9, it is not evident from the specification of the instant application what the Applicant is attempting to claim by stating "the hydroxyapatite-based material which forms the subject matter of patent EP-411 035 (and the corresponding application for an Italian patent BO2002A000650)." This statement renders the claim indefinite.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3, and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso 5,741,215 in view of Taboas et al. 2003/0006534.

9. D'Urso teaches a method of forming a prosthetic implant (abstract) that may be made of ceramics, or more specifically, hydroxyapatite (col. 5, ll. 29-33) (Claims 6, 9). D'Urso teaches using a CT scan of a patient to obtain a model showing the defect to be reconstructed (abstract) (claim 1), using prototyping to create a model of the defect (col. 4, ll. 26-33), forming the model, and constructing a mould or mould surface (negative mould) (col. 5, ll. 9-16). However, D'Urso does not teach the controlled porosity of the ceramic implant or a mechanical finishing step.

Taboas teaches a method of creating ceramic scaffolds that can support drug delivery (paragraph 7) (Claim 10) having direct or indirect solid free form (SFF)

Art Unit: 3738

fabrication. The scaffolds may have an interconnected porosity with pore dimensions .1-.125 microns and 125-2500 microns range (paragraphs 22-27) (Claim 1). Taboas also teaches manually processing a semi-finished product to obtain a final product (paragraph 12) (Claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of D'Urso with the ceramic scaffolds taught by Taboas in order to produce structures that mimic natural tissue properties as taught by Taboas (paragraph 7).

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso 5,741,215 in view of Taboas et al. 2003/0006534, as applied to claim 1 above, and further in view of Cummings et al. 2004/0152034.

11. D'Urso in view of Taboas teaches the invention as claimed and as discussed above. However, D'Urso in view of Taboas does not teach that the manual finishing is done with a diamond mill cutter.

Cummings teaches finishing a ceramic implant with a diamond milling cutter (paragraph 255).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of D'Urso in view of Taboas by using a diamond milling cutter as taught by Cummings because such a device is commonly known and used in the art for such a task.

Allowable Subject Matter

12. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/
Examiner, Art Unit 3738

/William H. Matthews/
Primary Examiner, Art Unit 3774

Application/Control Number: 10/594,941
Art Unit: 3738

Page 6